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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,262	05/06/2005	Kohji Yoshinaga	TSUZ 2 00021	1013

7590 07/17/2006

Jay R. Moldovanyi
Fay Sharpe Fagan Minnich & McKee
1100 Superior Avenue, 7th Floor
Cleveland, OH 44114-2518

EXAMINER

DO, PENSEE T

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/534,262	Applicant(s) YOSHINAGA ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-7 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/24/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on April 24, 2006 has been acknowledged and entered.

Claims 1-7 are pending.

Claims 1-4 are being examined.

Claims 5, 6 have been withdrawn.

Newly added claim 7 is being restricted.

Election/Restrictions

Newly submitted claim 7 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: elected claims 1-4 and claim 7 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the magnetic particle does not need the SQUID sensor in order to be functional. The subcombination has separate utility such as detection in bioassay.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 7 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Colin et al. (US 5,773,307).

Colin teaches a magnetic particle comprising of a metal core such as Fe₃O₄, encapsulated by a polymer such as carboxymethylcellulose (carboxyl groups). The diameter of the core ranges from 5 and 30 nm and the external diameter of the magnetic particle ranges between 20 nm and 900 nm. (see col. 3, lines 38-55; example I). Regarding the use of the magnetic marker with a SQUID magnetic sensor, since the magnetic marker of Colin has all the required features as those of the present invention, the magnetic marker of Colin can be used with a SQUID magnetic sensor as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 & 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colin et al.

Colin has been discussed above.

However, Colin fails to teach that the polymer has on the surface thereof, 500 to 5000 carboxyl groups per particle or 2000 to 3000 carboxyl groups.

Colin teaches the magnetic markers encapsulated with a polymer having carboxyl groups. It would have been obvious to one of ordinary skills in the art at the time the invention was made to have 500 to 5000 carboxyl groups on the surface of the polymer per particle since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skills in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed on April 24, 2006 have been fully considered but they are not persuasive.

Applicants argue that the claims now recite a magnetic marker composed of magnetic fine particle which exhibits residual magnetism and a polymer encapsulating the particle, for use in measuring an immunoreaction with a SQUID magnetic sensor. The particle diameter of the magnetic fine particle is 20 to 40 nm and the external diameter of the magnetic marker is 40 to 100 nm. The polymer has carboxyl groups on the surface thereof. However, Colin fails to teach a marker as presently claimed. Colin prefers the metal core to be free of residual magnetism and its mean size is between 5 and 30 nm, in particular between 10 and 20 nm (see col. 3, lines 40-42). Thus, the metal particles described in Colin are similar to the commercially available or conventionally known magnetic particles discussed in the present application in which

the diameter of the magnetic particle (metal core) is about to 10 to 15 nm, the external diameter is 50 to 1000 nm, and the detection is based on the superparamagnetism of the metal core. The meal particles disclosed in Colin would not serve as a highly-sensitive magnetic marker for use in measuring an immunoreaction with a SQUID magnetic sensor.

The specification of the present invention discloses that the size of magnetic particles encapsulated by a polymer should be larger than that of the commercially available magnetic fine particles mentioned previously; that is to say the diameter is required to be 20 to 40 nm. It also discloses that large magnetic particle exhibit residual magnetism. (see col. 6, second paragraph). Colin teaches that the average diameter of the whole magnetic particle encapsulated in a polymer is 20 nm to 100 nm (see col. 3, lines 55-56). Thus, the size of the magnetic reagent/particle in Colin is within the same range as those required by the present invention. The magnetic particles of Colin have average diameter size of 20 to 900 nm. (see example 1) and is encapsulated within a polymer with carboxyl groups. The external diameter is between 20 and 900 nm. (see example 1). Therefore, Colin's magnetic particle will exhibit residual magnetism and is capable of being used with a SQUID magnetic sensor. Colin teaches that the **metal core** is free of residual magnetism, not the overall particle.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Pensee T. Do
Patent Examiner
July 6, 2006


LONG V. LE 07/06/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600